As of July 2021

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ciclosporin	STN1007603 /DE-076C	Vernal keratoconjunctivitis	Original	U.S.					Jun-2021	
				China					Apr-2021	
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Launched successively in European countries since October 2018. Launched successively in Asian countries after receiving approval for an indication extension for Ikervis in August 2019. Launched in November 2019 in Canada. Received marketing apporval in June 2021 in U.S. and filed for marketing approval in April 2021 in China.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 /DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan						
A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Completed Phase 3 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010900 /DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia					Apr-2015	
An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Started an additional Phase 3 in December 2018 in the U.S. Filed for marketing approval in April 2015 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost/ timolol maleate	STN1011101 /DE-111A	Glaucoma/ Ocular hypertension	Co-development with AGC	China						
A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 in China.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepag isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.				Nov-2020		
				Japan						Nov-2018
				Asia						Feb-2021
An EP2 receptor agonist with a new mechanism of action. Filed for marketing approval in November 2020 in the U.S. Launched in November 2018 in Japan. Filed successively for marketing approval in Asian countries and launched in February 2021 in Korea.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	STN1012600 /DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.						
				Japan		(Phase 2b)				
A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Started an additional Phase 2 in December 2020 in the U.S. Completed Phase 2b in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012700 /DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan			(Phase 2/3)			
				Asia						
Non-selective muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2/3 in August 2019 in Japan. Completed Phase 2 in April 2020 in Asia.										

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100* /DE-128	Glaucoma	Original	Japan					May-2021	
				Europe						Apr-2019
				Asia					Mar-2020	
A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Filed for marketing approval in May 2021 in Japan. Launched in Europe in April 2019. Filed successively for marketing approval in Asian countries since March 2020. Received a rejection letter in Korea in April 2021; Considering re-filing.										

*Offered product development, commercialization, and sales rights to Glaukos in Americas, Australia and New Zealand in May 2021. Completed Premarket Approval rolling submission in June 2020. Received feedback from the Food and Drug Administration (FDA) on its assessment at the end of February 2021. Discussions with the FDA are ongoing. Received

marketing approval in March 2021 in Canada; preparing for a launch by Glaukos. Received marketing approval in May 2021 in Australia.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 /DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						
An ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative, for the treatment of glaucoma and ocular hypertension. Started Phase 3 trials in April 2019 in Europe and Asia.										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						
Selective muscarinic M2 antagonist which reduces juvenile myopia progression. Reduce mydriasis to selectively inhibit a subtype of receptors. Started Phase1 in July 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil dimesylate	STN1013900 /AR-13324	Glaucoma/ Ocular hypertension	Aerie	Japan						
A ROCK (Rho-associated kinase) inhibitor. Developed and marketed by Aerie in the U.S. Started Phase 3 in November 2020 in Japan.										

Changes from Q4 FY20 (May 11, 2021)

Dev. code	Changes
STN1007603 /DE-076C	Received marketing approval in June 2021 in U.S.
STN2000100 /DE-128	Filed for marketing approval in May 2021 in Japan.
STN1013400	Started Phase1 in July 2021 in Japan.

The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXXXX). AR-13324 is development code of Aerie Pharmaceuticals, Inc. (U.S.)